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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LIU, SUE XU	
ART UNIT	**PAPER NUMBER**
1639	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/668,600	BELCHER ET AL.	
	Examiner	Art Unit	
	Sue Liu	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-159* is/are pending in the application.

4a) Of the above claim(s) *8,9,13-15,18-20,30-111,116-118 and 121-159* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7, 10-12, 16, 17, 21-29, 112-115, 119 and 120* is/are rejected.

7)☒ Claim(s) *113-115,119 and 120* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/28/05;11/05/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Please note the change of examiner for this application. (Please see the Conclusion paragraph for information on any future correspondence.)

Claim Status

1. Claims 1-159 are currently pending;

Claims 8, 9, 13-15, 18-20, 30-111, 116-118, and 121-159 have been withdrawn;

Claims 1-7, 10-12, 16, 17, 21-29, 112-115, 119 and 120 are being examined in this application.

Election/Restrictions

2. Applicant's election of Group I (Claims 1-29 and 112-121) in the reply filed on 4/20/06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claims 30-111 and 122-159 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 4/20/06.

4. Applicants elected the following species:

A.)Virus as a biological material;

B.) One as the number of biological materials and protein as the additional biological material;

C.) Plastic as the substrate;

D.) Inorganic semiconductor as the species of molecule;

E.) Sugar as the type of stabilizer.

in the reply filed on 4/20/06 is acknowledged. Applicants further clarify the species election as the following in the reply filed on 8/17/06:

(a) "virus" as a biological material, (b) "zero" as the number of additional biological materials, (c) "plastic" as the substrate, (d) "inorganic" as the species of molecule, and (e) "sugar" as the type of stabilizer.

Accordingly, Claims 8, 9, 13-15, 18-20, 116-118, and 121 are withdrawn due to non-elected species. In addition, the nonelected species are withdrawn from each corresponding claim.

Priority

5. This application claims priority to U.S. Provisional Patent Application Nos. 60/413,081, filed 9/24/02.

Claim Objections

6. Claims 113-115, 119, and 120 are objected to because they are dependent on a claim (Claim 111) that has been withdrawn due to non-elected invention.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description Rejection

8. Claims 1-7, 10-12, 16, 17, 21-29, 112-115, 119 and 120 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims recite "a fabricated biofilm storage device for long term storage of material comprising: optionally, a substrate having a contacting surface, and a biologic material on the optional contacting surface and forming a stable film, wherein the film is stable at room temperature for at least 7 weeks."

To satisfy the written description requirement, applicants may convey reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention.

Applicants may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole. See, e.g., Vas-Cath, 935 F.2d at 1565, 19 USPQ2d at 1118.

The written description requirement of 35 U.SC. 112 exists independently of enablement requirement, and the requirement applies whether or not the case involves questions of priority.

The requirement applies to all inventions, including chemical inventions, and because the fact that the patent is directed to method entailing use of compound, rather than to compound per se, does not remove patentee's obligation to provide a description of the compound sufficient to distinguish infringing methods from non-infringing methods. See Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 920-23, 69 USPQ 2d 1886, 1890-93 (Fed. Cir. 2004).

With regard to the description requirement, applicants' attention is invited to consider the decision of the Court of Appeals for the Federal Circuit, which holds that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it form other materials." University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1405 (1997), quoting Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original) [The claims at issue in University of California v. Eli Lilly defined the invention by function of the claimed DNA (encoding insulin)].

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species or by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical an/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See Eli Lilly, 119 F. 3d at 1568, 43 USPQ2d at 1406.

The instant Claims are drawn to a genus of devices comprising a genus of "substrates", and a genus of "biologic materials", and device can further comprise a genus of inorganic

material. The instant specification defines the term "biologic material" as referring "to a virus, bacteriophage, bacteria, peptide, protein, amino acid, steroid, drug, chromophore, antibody, enzyme, single-stranded or double-stranded nucleic acid, vaccine, and any chemical modifications thereof." (p. 11 of the instant spec.). Thus, the instant application is claiming a product that can comprise biological materials that ranges from chemical compounds to whole organism.

Similarly, the instant specification also define the terms "substrate", and "inorganic molecule" very broadly (see pp. 12-13 of the instant spec.).

To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. (see MPEP 2163 II).

In this case, neither the instant specification nor the claims have demonstrated common structure and/or function for the claimed genus of "biologic material", the genus of "inorganic molecules", and the genus of "substrate". In addition, no representative numbers of species for each claimed genus is provided to show possession of the claimed genus of genes and genus of precursor molecules.

The only examples provided are devices generated using certain substrate with bacteriophage and certain inorganic molecules (p. 49+). All examples are described in the instants specification only use bacteriophage as the biologic material. Bacteriophage is not structurally and/or functionally representative of the instant claimed genus of "biologic material"

that includes other viruses as well as chemical and/or biological compounds. The success of the generation of the "biofilm" depends on the selection of the particular "biologic material" as reflected by the Examples of the instant specification. Without an appropriate "biologic material", "substrate", and "inorganic molecule", the claimed device cannot be generated. In addition, the art also does not teach all the possible "biologic material", "substrate", and "inorganic molecule" that can be used to generate the instantly claimed product.

Therefore, applicants are not in possession of the claimed genus of devices that comprise the claimed genuses of "biologic material", "substrate", and "inorganic molecule". Applicant's claimed scope represents only an invitation to experiment regarding possible materials that might be used to produce the claimed biofilm storage device.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-7, 10-12, 16, 17, and 21-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the phrase "optionally", which renders the claim indefinite because a person of skill in the art would not be able to define the metes and bounds of the claimed product. If a skilled artisan interpret the claim as to have no substrate, biological materials, etc., then it would not be clear as to what components are constitute by the claimed "storage device".

Claim 2 recites the phrase "based on time dependent infection ability of the biological material", which is indefinite. Neither the instant specification nor the claims specifically define the term "infection ability" or "time dependent infection ability".

Claim 20 recites the phrase "the biological material", which is unclear as to which material the term is referring. Claim 1 from which claim 20 depends on recites "biologic material" in line 4, and "material" in line 2. It is not clear if the term "the biological material' is referring to the made "biofilm" or the material that was used to make the film.

Claim 25 seems to recite alternative limitations, however, the claim is not written in an alternative format.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(Note: the instant claim numbers are in bold font.)

12. Claims 1-7, 10, 16, 17, 21-25, 27-29, 112-114, 119, and 120 are rejected under **35 U.S.C. 102(b)** as being anticipated by Campbell et al (US 5,958,430; 9/28/1999).

The instant claims recite "a fabricated biofilm storage device for long term storage of material comprising: optionally, a substrate having a contacting surface, and a biologic material on the optional contacting surface and forming a stable film, wherein the film is stable at room temperature for at least 7 weeks."

The instant Claim 1 recites that the claimed product "optionally" comprising a substrate and a biologic material that forms a film. Thus, the claimed product can be interpreted to encompass any "device" with intended use of storing biofilm.

Campbell et al, teach various substrates that can be used for storing biofilms (see Abstract), which reads on the "device" of **clm 1**.

Campbell et al, throughout the patent, teach generating a biofilm on a substrate (see Abstract). The reference teaches biofilms comprising peptide and inorganic crystalline structure (Claims 1-25 of the reference), which reads on the substrate and biologic material film of **clms 1-3, 6, 17, 23, 112** .

The recitations "forming a stable film" and "the film is stable at room temperature for at least 7 weeks" (**clms 1-3, 6**), anisotropic **(clm 17)**, and the various physico-chemical properties **(clm 23)** are inherent properties of the film and the biological material. The Campbell reference does not explicitly teach these properties of the film and the biological material. However, the claimed invention appears to be the same or obvious variations of the reference teachings, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to determine and/or compare the specific activities of the instant application versus the reference. In the absence of the evidence to the contrary, the burden is upon the applicant to prove that the claimed composition is different from the one

taught by prior art and to establish the patentable differences. See in re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ2d 1992(PTO Bd. Pat. App. & Int. 1989).

The reference also teaches using plastic as the substrate (see Abstract), which reads on **clm 4**.

The reference teaches drying the formed film (col. 3, lines 35+), which reads on **clm 5**.

The reference teaches inorganic crystalline is formed with the film of biological material (Abstract; Claims 1-25), which reads on **clms 7, 20, 22, 114, 119,** and **120**.

The reference teaches the substrate comprise alkenyl-silane (col. 3, lines 1+), which reads on the semiconductor of **clm 10**.

The reference teaches formation of thin film by immersing the wafer in solution (col. 3), and thus uniform thin film was formed, which reads on **clm 16**, and the product-by-process **clms 21, and 113**.

The reference's teaching (such as Claims 21-25 of the reference) also reads on the intended uses of **clm 24**.

The reference also teaches using various concentrations of stock solutions (col. 3), which reads on the product-by-process **clm 25**.

The reference teaches incubating the film in stock solution (col. 3, lines 35+), which reads on the intended use of storing the film in a storage solution of **clms 27** and **28**.

The reference also teaches detecting absorption of compounds in the film (col. 3, lines 40+), which reads on the intended use of **clm 29**.

"A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987)"

See MPEP 2114.

13. Claims 1-7, 10-12, 16, 17, 21-29, 112-115, 119 and 120 are rejected under **35 U.S.C. 102(a)** as being anticipated by Lee et al (Science. Vol. 296: 892-895; 5/3/2002; cited in IDS, filed 11/5/04).

Lee et al, throughout the publication, teach nanocrystal assembly using phage virus that bind to semiconductor substrates (see Abstract). The reference teaches biofilms formed using bacteriophage (virus) and ZnS (inorganic semiconductor material) (See Figures 1-4; p. 895), which reads on the substrate, the biofilm of virus, and the semiconductor material of **clms 1, 5-7, 10-12, 16, 20, 21, 22, 26, 112-115, 119,** and **120**.

The reference also teaches various properties of the biofilm (e.g. p. 892), which reads on the inherent properties recited in **clms 23, 25**.

The reference also teaches the stability of at least 7 months of the film, which reads on the inherent properties recited in **clms 2 and 3**.

The reference teaches epoxy resin (plastic) as the substrate (p. 865, right col.), which reads on **clm 4**.

The reference also teaches the virus has anisotropic shape (p. 892, middle col., para 2), which reads on the inherent property of the virus of **clm 17**.

The reference also teaches potential uses for the film (p. 895), which reads on the intended uses recited in **clm 24**

The reference's teachings also read on the intended use of the claimed biofilm as recited in **clms 27, 28** and **29**.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claims 1-7, 10-12, 16, 17, 21-29, 112-115, 119 and 120 are rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell et al (US 5,958,430; 9/28/1999) and Whaley et al (Nature. Vol. 405: 665-668. 6/8/2000; cited in IDS, filed 1/28/05).

Campbell et al, throughout the patent, teach generating a biofilm on a substrate, as discussed above.

Campbell et al do not explicitly teach the "biological material" is a virus as recited in **clms 11, 12,** and **115**, and the "biological material" genetically engineered as recited in **clm 26**.

However, Claim 26 is a product-by-process claim. Process steps *per se* cannot serve to limit the product claims. See In re Stephens, 345 F.2d 1020, 1023, 145 USPQ 656, 658 (CCPA 1965) ("We think it well settled that the presence of process limitations in product claims, which product does not otherwise patentably distinguish over the prior art, cannot impart patentability to that product."). The relevant inquiry in a product-by-process claim is how the process recitations might define structure. See, e.g., In re Garnero, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1969) (recitation of "interbonded one to another by interfusion between the surfaces of the perlite particles" construed as structural limitation in product claim); In re Dike, 394 F.2d 584, 589, 157 USPQ 581, 585 (CCPA 1968) (no error in USPTO board holding that term "blowmolded" in claims drawn to integral plastic container and handle failed to distinguish over

prior art, because term related to process of making the article, and was not definitive as to the structure of the article). Here, the process step "genetically engineered" does not add a structural limitation to the library because the resulting product of a biological material, the protein used by Campbell is not structurally different from the "biological material" recited in the instant application without evidence to the contrary. Thus, this process limitation does not impart patentability to the claimed library in accordance with In re Dike.

In addition, Whaley et al, throughout the publication, teach a similar biological material formation on substrates such as semiconductor through the formation of nanocrystal assembly as the one taught by Campbell et al (see Abstract of the reference). The reference teaches using bateriophage (a virus) in combination with inorganic material to form crystalline structure on a semiconductor substrate (see Figure 4, for example). The reference also teaches that the formed biological film has a surface area of 1-μm wide (p. 667, right col., para 2), which reads on thin uniform film.

Therefore, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to generate a device comprising a substrate, a biological film that comprises phage viruses and an inorganic material.

A person of ordinary skill in the art would have been motivated at the time of the invention to use phage virus in combination of inorganic material to form a film, because Whaley et al teach the phage virus crystalline formation would lead to useful products with "practically important materials" (Abstract of Whaley). Furthermore, the Whaley reference also teaches additional advantages of using phage in combination of inorganic materials to form structures on a substrate (p. 667, right col., para 5). The reference states the following: "These

organic-inorganic pairs should provide powerful building blocks for the fabrication of a new generation of complex, sophisticated electronic structures." Thus, one of ordinary skill in the art would have been motivated at the time of the invention to use phage virus in combination of inorganic material to form a film on a substrate depending on the application of the generated device.

A person of ordinary skill in the art would have reasonable expectation of success of achieving such modifications, because the formation of crystalline structure using phage and inorganic material on a substrate are known in the art as taught by Whale et al, and the general methods of generating biological films on a substrate (such as semiconductor or plastic material) are also known in the art such as the ones taught by Campbell et al.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sue Liu whose telephone number is 571-272-5539. The examiner can normally be reached on M-F 9am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JON EPPERSON
PRIMARY EXAMINER

SL
Art Unit 1639
1/17/2007

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